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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,732	10/06/2003	Tuoc Tan Nguyen	816020-100043-US	5302
34026	7590	10/05/2005		
JONES DAY 555 SOUTH FLOWER STREET FIFTIETH FLOOR LOS ANGELES, CA 90071			EXAMINER MILLER, CHERYL L	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 10/05/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/680,732

Applicant(s)

NGUYEN ET AL.

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/4/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: attachment 1.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-3 and 5-7 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "upper edges" in line 10. There is insufficient antecedent basis for this limitation in the claim. It is unclear what the "upper edges" are and where they are located. Applicant has only given reference to an inflow annulus, outflow annulus, and leaflets. It is unclear where the upper edges are in relation to the claimed limitations (inflow, outflow, distal, proximal the inflow or outflow, etc). Upper edges is being interpreted now, as being either the leaflet edges near the inflow or near the outflow. Claims 2, 3, and 5-7 depend upon claim 1 and inherit all problems associated with the claim.

It is also unclear which direction "below" is. For now it is being interpreted to be either near the inflow annulus or the outflow annulus (if applicant were to point out which inflow or outflow annulus is the top or bottom, or proximal or distal end, then below might have some relativity).

It is further noted to the applicant, that “not more than three vertical elements” is interpreted to be 0, 1, 2, or 3 vertical elements. It is requested of the examiner for the applicant to please point out where in the specification or drawings, the applicant has disclosed support for 0, 1, 2, or 3 vertical elements. If the applicant does not provide support, this will be a new matter issue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Gabbay (US 2003/0040792 A1, cited previously). Gabbay discloses an assembly (fig.2, 4) comprising a replacement valve (12) having leaflets (22, 24, 26) and a scalloped inflow annulus (inflow annulus is shown to be scalloped in all figures, but most clearly seen in figs. 1, 4, 15, 24) and an expandable anchoring structure (14) having flared rims (see fig.2, 1b, 11, 24), a rim positioned below upper edges of the valve leaflets (22, 24, 26) and flared away from the leaflets (a flare is shown at the edge of the rims, and opposite portions of the rims are coextensive with the valve, thus below upper edges of valve; see attachment 1), and not more than three vertical elements (not more than three is interpreted to be 0, 1, 2, or 3; therefore zero vertical elements of Gabbay reads on the claim) extending between the rims. Gabbay discloses the valve (12) to be

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positioned internal of the anchor structure (see figs). Gabbay discloses the inflow rim of the anchor structure to have one or more rings in undulating patterns. Gabbay's elements are *configured* to coincide with sinus commissural posts of the native valve (no elements exist and elements are not required by claim 1, therefore, also not required by claim 7, since they have not been positively claimed).

Claims 1-3, 5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Leonhardt et al. (US 5,957,949, cited previously). Leonhardt discloses an assembly (fig.4) comprising a replacement valve (22) having leaflets (see fig.4) and a scalloped inflow annulus (inflow annulus is shown to be scalloped in figs.4) and an expandable anchoring structure (26) having flared rims (see fig.2, 9D), a rim positioned below upper edges of the valve leaflets (see fig.4; it is noted to the applicant, that the claim is not clear as to which rim, the inflow or outflow, is positioned below the valve leaflets. Also, it is noted to the applicant, that the upper edges of the valve have no antecedent basis and may be considered to be near the inflow or outflow; it is also unclear whether "below" means near the inflow or outflow annulus) and flared away from the leaflets (a flare is shown at the edge of the rims, and the flared portions extend away from the valve leaflets), and not more than three vertical elements (not more than three is interpreted to be 0, 1, 2, or 3; Leonhardt has shown one, 29, in fig.1a, 1b; and discloses one or more, col.12, lines 40-45) extending between the rims. Leonhardt discloses the valve (22) to be positioned internal of the anchor structure (26). Leonhardt discloses the inflow rim of the anchor structure to have one or more rings in undulating patterns (anchor 26 is shown to have one ring

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in fig.1a, 1b). Leonhardt's elements are *configured* to coincide with sinus commissural posts of the native valve.

Claims 1-3, 5, and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Quijano et al. (US 2004/02110306 A1). Quijano discloses an assembly (fig.4, 7, 8) comprising a replacement valve having leaflets (13) and a scalloped inflow annulus (inflow annulus is shown to be scalloped in fig.4, 7, 8) and an expandable anchoring structure (21, 22) having flared rims (21, 22, fig.7 shows flaring), a rim positioned below upper edges of the valve leaflets (see for instance rim 21 positioned as so in fig.8) and flared away from the leaflets (a flare is shown at the edge of the rims, and the flared portions extend away from the valve leaflets; see fig.7), and not more than three vertical elements (not more than three is interpreted to be 0, 1, 2, or 3; Quijano has shown three, 27, in fig.4, 7, 8) extending between the rims (21, 22). Quijano discloses the valve (12+13) to be positioned internal of the anchor structure (21+22; see figs). Quijano discloses the inflow rim of the anchor structure to have one or more rings in undulating patterns (fig.4, 7, 8, shows rims with a generally hexagonal shape when expanded). Quijano's elements are *configured* to coincide with sinus commissural posts of the native valve (is configured to be placed anywhere within a vessel).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gabbay (US 2003/0040792 A1) or Leonhardt et al. (US 5,957,949) or Quijano et al. (US 2004/0210306 A1). All of Gabbay, Leonhardt, and Quijano disclose a valve assembly comprising an expandable anchoring structure having a pattern of either a zig-zag (sinusoidal) shape (Leonhardt), or a diamond mesh shape (Gabbay), or a hexagonal mesh shape (Quijano). However, none of the above reference disclose an expandable anchoring structure having a pattern of both hexagons and diamonds in combination. At the time the invention was made it would have been obvious to a person of ordinary skill in the art to make an expanding anchor (stent) with a diamond/hexagon shaped pattern. Applicant has not disclosed that a hexagon/diamond combination pattern provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either a sinusoidal, diamond, or hexagon pattern, because all are expanding structural patterns.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER

Attachment #1 (markedup)

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